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## URGENT: DRUG RECALL

September 8, 2006

Event: 1659

**Pharmacy and wholesaler level recall of specific lots of Paxil CR® (Paroxetine Hydrochloride) Controlled Release Tablets.**

Dear Customer:

GlaxoSmithKline is recalling the following products **from the retail and wholesale levels for the referenced lot numbers only:**

Product	Strength	Lot Number	NDC	Package Size
Paxil CR® Tablets	37.5 mg	303-6P08	0029-3208-13	Bottle 30's
Paxil CR® Tablets	37.5 mg	304-6P08	0029-3208-13	Bottle 30's
Paxil CR® Tablets	37.5 mg	305-6P08	0029-3208-13	Bottle 30's

The above referenced Paxil CR® Tablet batches are being recalled due to an intermittent manufacturing equipment malfunction which may result in some tablets containing no active ingredient.

Please examine your inventory immediately and return all product detailed above, from the **referenced lot numbers only**, using the enclosed UPS shipping labels to GlaxoSmithKline, c/o Stericycle Pharmaceutical Services, 2670 Executive Drive, Suite A, Indianapolis, IN 46241. Stop distributing and immediately quarantine the referenced lot numbers only. Please carry out a physical count and record this data on the business reply card and the packing slip which are included with this letter. It is very important that you complete the requested information on the enclosed postage paid Business Reply Card and return to us within five (5) business days, **even if you do not have the referenced lots in stock.**

Thank you for your cooperation. For shipping assistance or questions about the recall process, please contact Stericycle Pharmaceutical Services at 1-866-324-3735. A check will be issued for the price in effect at the time of purchase. In addition, a service and handling charge will be included based on HDMA guidelines. If you have any medical questions, please contact the GlaxoSmithKline Customer Response Center at 1-888-825-5249 between 8:00 a.m. and 8:00 p.m. ET, Monday through Friday.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation. GlaxoSmithKline remains committed to product quality, integrity, and patient satisfaction and we sincerely regret any inconvenience this action may cause.

Enclosures: Postage Paid Business Reply Card  
Packing Slip and Prepaid UPS Authorized Return Service Shipping Label